

**REMARKS****I. Introduction**

Upon entry of the present amendment, claims 1, 2, 11-14 and 16-27 will be pending in this application. Claims 1 and 2 have been amended to more fully define the invention and to clarify that the inflammation being treated or prevented is caused (or the patient is at risk from inflammation caused) by one or more of immune-mediated inflammation, osteoarthritis, rheumatoid arthritis, glomerulonephritis, colitis, or cystitis. Support for this amendment appears in the specification at least at pages 3 and 4.

Applicants have also added newly presented claims 22 - 27. The Examiner has indicated that claims 22 and 23 are fully supported by the specification (*see* Office action at page 6), and claims 24-27 further define features of those claims. No new matter has been added.

**II. 35 U.S.C. § 112****A. Preventing vs. treating inflammation**

The Examiner has rejected claims 2, 12, 14, 17, 19, and 21 under 35 U.S.C. § 112, first paragraph, as being unsupported by the specification. The Examiner states that the specification does not disclose any examples which indicate that the method can be used to prevent inflammation, but only indicates that the composition can be used to treat animals that already have inflammation. Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

Examples 3 and 4 specifically show how mycobacterium can be used to treat animals to prevent inflammation. Example 3 discloses an experiment in which MCC was administered initially. Two hours *after* that administration, a solution of carrageenan was

injected to induce inflammation. *See* specification at page 8. Likewise, Example 4 discloses an experiment in which "subcutaneous administration of MCC into the hind footpad, 2 h before carrageenan injection into the same hind footpad, also reduced inflammation." *See* specification at page 9. Accordingly, Applicants have indeed shown how the claims can be used to prevent inflammation, and it is respectfully requested that this rejection be withdrawn.

#### **B. Enablement of inflammation treatment**

The Examiner has also rejected claims 1, 11, 13, 16, 18, and 20 under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification. The Examiner indicates that inflammation encompasses a very broad class of diseases which can be caused by many factors that can stimulate inflammation through a variety of different responses. The Examiner's position is that there is no indication that any compound can be used to effectively treat any type of inflammation.

While not acquiescing to the correctness of the Examiner's rejections and in the interest of advancing the prosecution of this case, Applicants have amended claim 1 to recite certain types of inflammation that can be treated in accordance with this invention. Applicants respectfully request that this rejection be withdrawn.

#### **III. 35 U.S.C. § 101**

The Examiner rejected claims 2, 12, 14, 17, 19, and 21 under 35 U.S.C. § as not constituting a well-established utility. The Examiner's position is that the claimed method of preventing inflammation does not constitute a substantial utility because one of skill in the art would not recognize that any substance could be used to prevent inflammation without the first completing additional experimentation.

While not acquiescing to the correctness of the Examiner's rejections and in the interest of advancing the prosecution of this case, Applicants have amended claim 2 to recite certain types of inflammation that can be treated in an animal at risk for those types of inflammation accordance with this invention. Applicants respectfully request that this rejection be withdrawn.

### CONCLUSION

For at least the above reasons, Applicant respectfully requests allowance of claims 1, 2, 11-14 and 16-27 and issuance of a patent containing these claims in due course. If there remain any additional issues to be addressed, the Examiner is urged to contact the undersigned attorney.

Respectfully submitted,



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